

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 03 August 2001 (03.08.01)	
International application No. PCT/GB00/04288	Applicant's or agent's file reference P701479/AJC
International filing date (day/month/year) 08 November 2000 (08.11.00)	Priority date (day/month/year) 11 November 1999 (11.11.99)
Applicant NICKSON, Shane, Willard	

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1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

28 May 2001 (28.05.01)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Juan Cruz Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P701479/AJC	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/GB 00/ 04288	International filing date (day/month/year) 08/11/2000	(Earliest) Priority Date (day/month/year) 11/11/1999
Applicant TYCO HEALTHCARE UK LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 2 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

ANKLE/ FOOT ORTHOSIS

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1

☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 00/04288

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F5/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	✓ WO 98 34572 A (ENGDAHL KARL ;WILLNER STIG (SE)) 13 August 1998 (1998-08-13) cited in the application abstract page 3, line 15 -page 7, line 11; figures 1-3	1-4, 6, 10
A	✓ US 5 219 324 A (HALL CHARLES) 15 June 1993 (1993-06-15) column 4, line 6 -column 5, line 24; figure 1	1, 4
A	✓ US 5 759 168 A (BUSSELL MARK H ET AL) 2 June 1998 (1998-06-02) column 1, line 38 -column 56 column 3, line 19 -column 4, line 44; figure 1	1

☐

Further documents are listed in the continuation of box C.

☒

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

12 January 2001

Date of mailing of the international search report

01/02/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Arjona Lopez, G

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/04288

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9834572	A	13-08-1998	US 5897515 A	27-04-1999
			AU 3871897 A	26-08-1998
			CN 1245411 A	23-02-2000
			EP 1005297 A	07-06-2000
			NO 993737 A	05-10-1999
			PL 335088 A	10-04-2000

US 5219324	A	15-06-1993	CA 2131885 A	16-09-1993
			DE 9390060 U	15-12-1994
			WO 9317641 A	16-09-1993

US 5759168	A	02-06-1998	US 5775008 A	07-07-1998

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
17 May 2001 (17.05.2001)

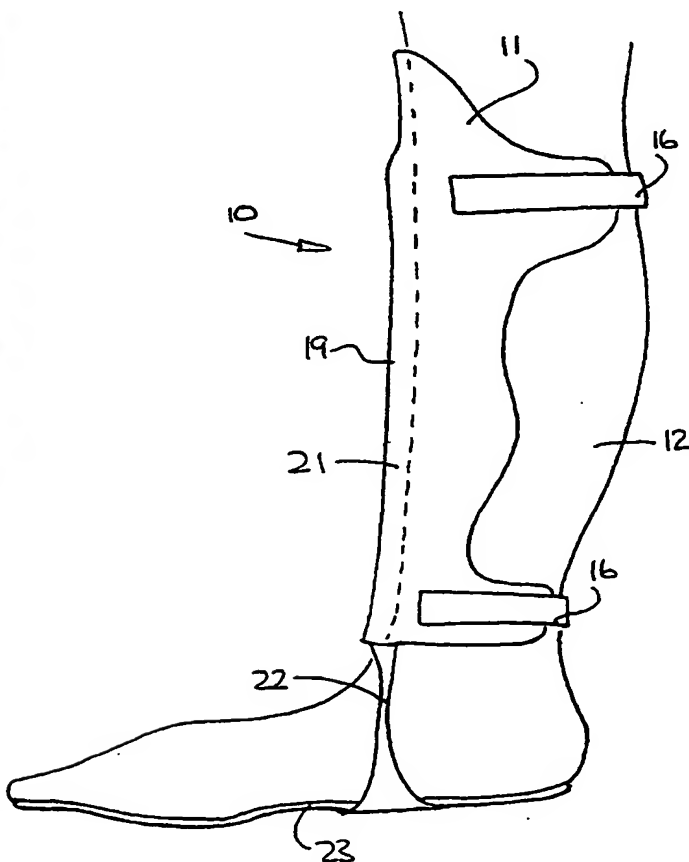
PCT

(10) International Publication Number
WO 01/34071 A1

- (51) International Patent Classification⁷: **A61F 5/01**
- (21) International Application Number: **PCT/GB00/04288**
- (22) International Filing Date:
8 November 2000 (08.11.2000)
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data:
9926599.3 11 November 1999 (11.11.1999) **GB**
- (71) Applicant (for all designated States except US): **TYCO HEALTHCARE UK LIMITED [GB/GB]; 154 Fareham Road, Gosport, Hampshire PO13 OAS (GB).**
- (72) Inventor; and
(75) Inventor/Applicant (for US only): **NICKSON, Shane, Willard [GB/GB]; 54 Glenorchy Road, Carterknowle, Sheffield S7 2EL (GB).**
- (74) Agents: **CHETTLE, Adrian, John et al.; Withers & Rogers, Goldings House, 2 Hays Lane, London SE1 2HW (GB).**
- (81) Designated States (national): **AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.**
- (84) Designated States (regional): **ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian**

[Continued on next page]

(54) Title: **ANKLE/FOOT ORTHOSIS**



(57) Abstract: An ankle/foot orthosis (10) has a strapping member (11) for the lower leg, an inflexible anterior longitudinal stiffener (21), a sole plate (23), and a relatively flexible strut (22) connecting the stiffener (21) to the sole plate (23). The flexible strut (22) permits a degree of ankle flexibility, and promotes a more natural walking gait.

WO 01/34071 A1



patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *With international search report.*

A. CLASSIFICATION OF SUBJECT MATTER

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EPO-Internal

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A	US 5 219 324 A (HALL CHARLES) 15 June 1993 (1993-06-15) column 4, line 6 -column 5, line 24; figure 1	1,4
A	US 5 759 168 A (BUSSELL MARK H ET AL) 2 June 1998 (1998-06-02) column 1, line 38 -column 56 column 3, line 19 -column 4, line 44; figure 1	1

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *Z* document member of the same patent family

Date of the actual completion of the international search

12 January 2001

Date of mailing of the international search report

01/02/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Arjona Lopez, G

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/04288

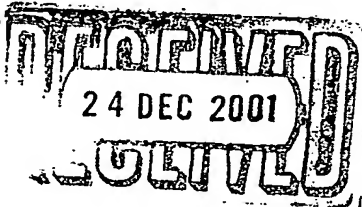
Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9834572 A	13-08-1998	US 5897515 A	27-04-1999
		AU 3871897 A	26-08-1998
		CN 1245411 A	23-02-2000
		EP 1005297 A	07-06-2000
		NO 993737 A	05-10-1999
		PL 335088 A	10-04-2000
US 5219324 A	15-06-1993	CA 2131885 A	16-09-1993
		DE 9390060 U	15-12-1994
		WO 9317641 A	16-09-1993
US 5759168 A	02-06-1998	US 5775008 A	07-07-1998

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

CHETTLÉ Adrian John
WITHERS & ROGERS
Goldings House
2 Hays Lane
London SE1 2HW
GRANDE BRETAGNE



PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing (day/month/year)	19.12.2001
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Applicant's or agent's file reference ./.	IMPORTANT NOTIFICATION
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International application No. PCT/GB00/04288	International filing date (day/month/year) 08/11/2000	Priority date (day/month/year) 11/11/1999
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Applicant TYCO HEALTHCARE UK LIMITED et al.
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1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
---------------------------------------	--------------------



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Ertl, L

Tel. +49 89 2399-7447



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference J.	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB00/04288	International filing date (day/month/year) 08/11/2000	Priority date (day/month/year) 11/11/1999	
International Patent Classification (IPC) or national classification and IPC A61F5/01			
Applicant TYCO HEALTHCARE UK LIMITED et al.			


1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 28/05/2001	Date of completion of this report 19.12.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Arjona Lopez, G Telephone No. +49 89 2399 2546



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/04288

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-3 as originally filed

4,5 as received on 08/10/2001 with letter of 04/10/2001

Claims, No.:

1-12 as received on 08/10/2001 with letter of 04/10/2001

Drawings, sheets:

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/04288

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-12
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-12
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-12
	No:	Claims	

2. Citations and explanations
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/04288

To point V:

1. Reference is made to following documents:

D1: WO-A-98/34572

D2: US-A-5 219 324

D3: US-A-5 759 168

2. Document D1, which is considered to represent the most relevant state of the art, discloses (cf. abstract; figures 1-3; page 3, line 15-page 7, line 11) an ankle/foot orthosis comprising a strapping member (1) for a lower leg, and having an inflexible anterior longitudinal stiffener (3), a sole plate (5) and a strut (4) connecting the longitudinal stiffener (3) and the sole plate (5), the strut (4) extending to the sole plate (5) at the outer side thereof and anterior of the position of the ankle, from which the subject-matter of claim 1 differs in that

a)- the strut is flexible.

- 2.1 The subject-matter of claim 1 is therefore novel (Article 33(2) PCT).

- 2.2 The problem to be solved by the present invention may therefore be regarded as to provide an ankle/foot orthosis with an improved flexibility.

- 2.3 The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons: The problem of providing flexibility to the orthosis is addressed in documents D2 and D3. Document D2 (cf. figure 1; column 5, lines 12-20) proposes to increase the flexibility by controlling the amount and thickness of the material of the brace in the area of the yoke pad and the dorsal end. Document D3 (cf. figures 1-2; column 3, lines 19-38) proposes a one piece flexible brace. By combining the teachings of document D1 and D2, the man skilled in the art would arrive to a foot/ankle orthosis with a flexible yoke but still a rigid strut, while combining the teachings of documents D1 and D3 would result in the removal of the inflexible reinforcement (3) of the device of D1, and therefore, in an flexible orthosis without an anterior longitudinal stiffener.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/04288

3. Claims 2-12 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

From the base of the stiffener 21 extends a strut 22 to which is provided a sole plate 23. Both the strut and the sole plate are of glass fibre reinforced resin, but the sole plate may include aramid or carbon fibres in order to improve the toughness and rigidity of selected areas. In particular the mid-region of the sole plate may be rather inflexible whereas the toe and heel regions may be relatively flexible so as to improve the gait of a wearer. Flexibility of the sole plate may be varied by changing the direction of reinforcement fibres. The periphery of the sole plate may be solely of glass fibre to permit relatively easy trimming to size thereof.

10

The strut 22 is about 3mm thick at the ends, and has a circular section of about 8mm diameter in the mid-region. The change of strut section is smooth and the ends of the strut are smoothly radiussed into the stiffener and sole plate. During lay-up of the orthosis the fibres are integrated and overlapped to provide an essentially seamless construction.

15

The sole plate can be of any suitable shape, and typically has a thickness of 0.3-2.0mm.

The stiffener 21 is fixed to the strapping member 11 by rivets or screws 24. A plurality of fixing positions may be provided to allow adjustment for length of leg, for example a slot may be provided in the strapping member to allow for adjustment prior to permanent attachment.

20

Manufacture of the orthosis is by moulding the stiffener, strut and sole plate as a unit, the fibres being laid up in a mould or cut from pre-preg sheet. After curing, this component is trimmed to size if necessary. Trimming may be cosmetic, or can be used to influence the degree of flexibility imparted by the strut 22.

25

Thereafter the strapping portion is attached, after suitable measurement of a patient. Final fitting includes trimming of the sole plate, and moulding or trimming of the strapping portion.

30

To attach the orthosis, straps 16 are passed through the buckles 13, and the portions 18 laid over the portions 17 to the required degree of tightness. The straps 16 may finally be trimmed to a reasonable length.

- 5 Figure 3 shows a graphical representation of the gait of a typical wearer of the preferred embodiment. The 'X' axis shows time in seconds, and the 'Y' axis shows percentage of body weight. This gait approximates closely to a normal gait, the first peak indicating a distinct heel strike, and the second peak indicating a distinct toe strike. The forces generated approach those of a normal gait thus giving the user the appearance of walking normally. The overall time for a step at normal walking pace is about the same as for an undiseased person, thus permitting an approximately even walking pace where only one leg of the person requires support.
- 10

Various modification to the embodiment will occur to the skilled man within the scope of the appended claims.

15

Claims

CLAIMS

- 5 1. An ankle/foot orthosis comprising a strapping member (11) for a lower leg, and having an inflexible anterior longitudinal stiffener (21), a sole plate (23), and a strut (22) connecting the longitudinal stiffener (21) and the sole plate (23), the strut (22) extending to the sole plate (23) at the outer side thereof, and anterior of the position of the ankle, characterized in that said strut (22) is flexible.
- 10
2. An ankle/foot orthosis according to claim 1 wherein the flexible portions of the orthosis are manufactured substantially of glass fibre or aramid fibre reinforced resin, and the inflexible portion is manufactured in carbon fibre reinforced resin.
- 15 3. An ankle/foot orthosis according to claim 1 or claim 2 wherein the rigidity of sole plate (23) varies over the area thereof, portions being inflexible, and portions being flexible so as to give support to the foot whilst allowing bending of the toes.
- 20 4. An ankle/foot orthosis according to any preceding claim wherein the strapping member (11) is adapted to extend around the sides of a leg, and has securing straps adapted to accommodate variation in leg thickness.
- 25 5. An ankle/foot orthosis according to claim 4 wherein said strapping member (11) is moulded from a soft thermoplastic so as to be mouldable by application of heat
6. An ankle/foot orthosis according to any preceding claim wherein said strut (22) is encased.
- 30 7. An ankle/foot orthosis according to claim 6 wherein the strut (22) is encased in a sleeve of plastics material.
8. An ankle/foot orthosis according to claim 7 wherein said sleeve is heat shrinkable so as to mould itself tightly to the contours of the strut (22).

9. An ankle/foot orthosis according to any preceding claim wherein fasteners (24) are provided whereby the stiffener (21) is movable longitudinally of the strapping member (11).

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10. An ankle/foot orthosis according to claim 9 wherein said stiffener (21) is on the inside of said strapping member (11).

11. An ankle/foot orthosis according to claim 10 wherein said stiffener (21) resides in a channel (19) of the strapping member (11).

10

12. An ankle/foot orthosis according to claim 11 wherein said channel (19) is open at the bottom.

15

REPLACED BY
ART 34 AMDT

PATENT COOPERATION TREATY

REC'D 21 DEC 2001

WIPO

PCT

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12

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference ./.	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/04288	International filing date (day/month/year) 08/11/2000	Priority date (day/month/year) 11/11/1999
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- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 28/05/2001	Date of completion of this report 19.12.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Arjona Lopez, G Telephone No. +49 89 2399 2546 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/04288

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-3 as originally filed

4,5 as received on 08/10/2001 with letter of 04/10/2001

Claims, No.:

1-12 as received on 08/10/2001 with letter of 04/10/2001

Drawings, sheets:

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/04288

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-12
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-12
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-12
	No:	Claims	

- 2. Citations and explanations
see separate sheet**

To point V:

1. Reference is made to following documents:

D1: WO-A-98/34572

D2: US-A-5 219 324

D3: US-A-5 759 168

2. Document D1, which is considered to represent the most relevant state of the art, discloses (cf. abstract; figures 1-3; page 3, line 15-page 7, line 11) an ankle/foot orthosis comprising a strapping member (1) for a lower leg, and having an inflexible anterior longitudinal stiffener (3), a sole plate (5) and a strut (4) connecting the longitudinal stiffener (3) and the sole plate (5), the strut (4) extending to the sole plate (5) at the outer side thereof and anterior of the position of the ankle, from which the subject-matter of claim 1 differs in that

a)- the strut is flexible.

- 2.1 The subject-matter of claim 1 is therefore novel (Article 33(2) PCT).
- 2.2 The problem to be solved by the present invention may therefore be regarded as to provide an ankle/foot orthosis with an improved flexibility.
- 2.3 The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons: The problem of providing flexibility to the orthosis is addressed in documents D2 and D3. Document D2 (cf. figure 1; column 5, lines 12-20) proposes to increase the flexibility by controlling the amount and thickness of the material of the brace in the area of the yoke pad and the dorsal end. Document D3 (cf. figures 1-2; column 3, lines 19-38) proposes a one piece flexible brace. By combining the teachings of document D1 and D2, the man skilled in the art would arrive to a foot/ankle orthosis with a flexible yoke but still a rigid strut, while combining the teachings of documents D1 and D3 would result in the removal of the inflexible reinforcement (3) of the device of D1, and therefore, in an flexible orthosis without an anterior longitudinal stiffener.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/04288

3. Claims 2-12 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

From the base of the stiffener 21 extends a strut 22 to which is provided a sole plate 23. Both the strut and the sole plate are of glass fibre reinforced resin, but the sole plate may include aramid or carbon fibres in order to improve the toughness and rigidity of selected areas. In particular the mid-region of the sole plate may be rather inflexible whereas the toe and heel regions may be relatively flexible so as to improve the gait of a wearer. Flexibility of the sole plate may be varied by changing the direction of reinforcement fibres. The periphery of the sole plate may be solely of glass fibre to permit relatively easy trimming to size thereof.

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The strut 22 is about 3mm thick at the ends, and has a circular section of about 8mm diameter in the mid-region. The change of strut section is smooth and the ends of the strut are smoothly radiussed into the stiffener and sole plate. During lay-up of the orthosis the fibres are integrated and overlapped to provide an essentially seamless construction.

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The sole plate can be of any suitable shape, and typically has a thickness of 0.3-2.0mm.

The stiffener 21 is fixed to the strapping member 22 by rivets or screws 24. A plurality of fixing positions may be provided to allow adjustment for length of leg, for example a slot may be provided in the strapping member to allow for adjustment prior to permanent attachment.

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Manufacture of the orthosis is by moulding the stiffener, strut and sole plate as a unit, the fibres being laid up in a mould or cut from pre-preg sheet. After curing, this component is trimmed to size if necessary. Trimming may be cosmetic, or can be used to influence the degree of flexibility imparted by the strut 22.

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Thereafter the strapping portion is attached, after suitable measurement of a patient. Final fitting includes trimming of the sole plate, and moulding or trimming of the strapping portion.

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To attach the orthosis, straps 16 are passed through the buckles 13, and the portions 18 laid over the portions 17 to the required degree of tightness. The straps 16 may finally be trimmed to a reasonable length.

- 5 Figure 3 shows a graphical representation of the gait of a typical wearer of the preferred embodiment. The 'X' axis shows time in seconds, and the 'Y' axis shows percentage of body weight. This gait approximates closely to a normal gait, the first peak indicating a distinct heel strike, and the second peak indicating a distinct toe strike. The forces generated approach those of a normal gait thus giving the user the appearance of
- 10 walking normally. The overall time for a step at normal walking pace is about the same as for an undischabled person, thus permitting an approximately even walking pace where only one leg of the person requires support.

- Various modification to the embodiment will occur to the skilled man within the scope
- 15 of the appended claims and without departing from the essence of the present invention.

Claims

CLAIMS

- 5 1. An ankle/foot orthosis comprising a strapping member for a lower leg, and having an inflexible anterior longitudinal stiffener, a sole plate, and a relatively flexible strut connecting the longitudinal stiffener and the sole plate, the strut extending to the sole plate at the outer side thereof, and anterior of the position of the ankle.
- 10 2. An ankle/foot orthosis according to claim 1 wherein the flexible portions of the orthosis are manufactured substantially of glass fibre or aramid fibre reinforced resin, and the rigid portion is manufactured in carbon fibre reinforced resin.
- 15 3. An ankle/foot orthosis according to claim 1 or claim 2 wherein the rigidity of sole plate varies over the area thereof, portions being relatively rigid, and portions being relatively flexible so as to give support to the foot whilst allowing bending of the toes.
- 20 4. An ankle/foot orthosis according to any preceding claim wherein the strapping member is adapted to extend around the sides of a leg, and has securing straps adapted to accommodate variation in leg thickness.
- 25 5. An ankle/foot orthosis according to claim 4 wherein said strapping member is moulded from a soft thermoplastic so as to be mouldable by application of heat
- 30 6. An ankle/foot orthosis according to any preceding claim wherein said flexible strut is encased.
7. An ankle/foot orthosis according to claim 6 wherein the flexible strut is encased in a sleeve of plastics material.
8. An ankle/foot orthosis according to claim 7 wherein said sleeve is heat shrinkable so as to mould itself tightly to the contours of the strut.

9. An ankle/foot orthosis according to any preceding claim wherein fasteners are provided whereby the stiffener is movable longitudinally of the strapping member.
10. An ankle/foot orthosis according to claim 9 wherein said stiffener is on the inside
5 of said strapping member.
11. An ankle/foot orthosis according to claim 10 wherein said stiffener resides in a channel of the strapping member.
- 10 12. An ankle/foot orthosis according to claim 11 wherein said channels open at the bottom.